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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,839	06/15/2000	James Anthony	2629-4017	3097
27123 7590 11/15/2007 MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER CHUNDURU, SURYAPRABHA	
			ART UNIT 1637	PAPER NUMBER
			NOTIFICATION DATE 11/15/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/594,839	Applicant(s) ANTHONY ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 26-36 and 38-55 is/are pending in the application.
- 4a) Of the above claim(s) 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26-36, 38-46 and 48-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/26/07 & 9/4/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action filed on September 04, 2007 has been entered.

Status of the Application

2. Claims 1-24, 26-36, 38-46, 48-55 are currently pending. Claim 47 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive for the reasons that follow. This action is made Non-Final.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-23, 30-31, 36, 40-41, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazzulli et al. (J Clin Microbiol., Vol. 37, No. 4, pp. 958-963, April 1999).

Mazzulli et al. teach a method of claims 22, 40, 42, for detecting a target nucleic acid comprising

(a) hybridizing a single-stranded target nucleic acid to a capture sequence probe (RNA probe) and an unlabeled signal sequence probe (RNA probe), wherein the capture probe and signal probe hybridizes to non-overlapping regions within the target and do not hybridize to each other, wherein said hybridization forms DNA-RNA hybrid with said probes (see page 958, col. 2, paragraph 1, indicating use of unlabeled RNA probes (implies two or more probes, herein

characterized to include capture probe and signal probe), page 959, col. 1, paragraph 1, line 12-24, indicating the probe mix is different from carrier calibrators);

(b) binding the hybrid complex to an antibody which binds to the DNA-RNA hybrid of the hybrid complex, wherein the antibody is detectable labeled (see page 959, col. 1, paragraph 1, line 21-30);

(c) detecting the target nucleic acid (see page 959, col. 1, paragraphs 1-2).

With regard to claim 30, Mazzulli et al. teach that the method comprises the step of forming single-stranded target DNA (denaturing step) prior to hybridization step (see page 959, line 12-15 of paragraph 1).

With regard to claim 31, Mazzulli et al. teach that the capture and signal probes are added sequentially (see page 959, col. 1, paragraph 1).

With regard to claim 36, Mazzulli et al. teach that said antibody is labeled with alkaline phosphatase (see page 959, col. 1, paragraph 1).

With regard to claim 23, 41, the method comprises capturing the hybrid on to a solid surface to form a bound hybrid complex (see page 959, col. 1, paragraph 1).

Accordingly Mazzulli et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 24, 26-27, 34-35, 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzulli et al. (J Clin Microbiol., Vol. 37, No. 4, pp. 958-963, April 1999) in view of Brakel et al. (US 5,082,830).

Mazzulli et al. teach a method for detecting a target nucleic acid as discussed above in section 3.

However Mazzulli et al. did not teach labeling capture probe with biotin labels at each of the 5' and 3' ends of the probe, and binding with streptavidin.

Brakel et al. teach a method of detecting a target nucleic acid wherein Shah et al. disclose that the method comprises hybridizing a target nucleic acid (DNA or RNA) with an biotinylated oligonucleotide which comprises at least one biotin on each of the 5' and 3' end nucleotides (see col. 2, line 10-17) and is used in detection of the target by combining with a streptavidin for enhancing the signal reporting moiety (see col.3, line 41-67, col. 4, line 1-11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting a target nucleic acid as taught by Mazzulli et al. with the step of adding probes with end labeled biotins as taught by Brakel et al.

to achieve expected benefit of enhancing the signal generating moieties for detecting nucleic acid target because one skilled in the art would have a reasonable expectation of success that the combination would result in signal amplification because Brakel et al. explicitly taught that oligonucleotides containing biotin labels near or at the ends of the hybridizing sequence were more effective than the oligomers with internal biotin labels (see col. 4, line 6-11) and such modification is considered obvious over the cited prior art.

B. Claims 28-29, 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzulli et al. (J Clin Microbiol., Vol. 37, No. 4, pp. 958-963, April 1999) in view of Collins et al. (USPN. 5,750,338).

Mazzulli et al. teach a method for detecting a target nucleic acid as discussed in section 3.

However Mazzulli et al. did not teach the hybridizing distance between the hybridizing probes on the target, and hybridization conditions.

Collins et al. teach a method of claim 1-2, 37-38, 40, 46, of detecting a target nucleic acid wherein Collins et al. teach that the method comprises (i) the capture sequence probe and signal sequence probe hybridize to regions of the target nucleic acid comprising less than 500 bases apart (see col. 19, line 32-38); and (ii) hybridization is carried out at room temperature (see col. 28, line 9-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting a target nucleic acid as taught by Mazzulli et al. with the step of adding hybridization conditions as taught by Collins et al. to achieve expected benefit of enhancing the hybridization for detecting nucleic acid target because one skilled in the art would have a reasonable expectation of success that the combination would

result in enhancing the hybridization between the target and the hybridization probes and reduce the non-specific binding because Collins et al. explicitly taught that the method provides reduction in the background noise (see col. 6, line 42-54, col. 9, line 42-53) and such modification is considered obvious over the cited prior art. Further, As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of hybridization conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Response to arguments:

5. With regard to the rejection of claims 34-35 under 35 USC 112, second paragraph, Applicants' arguments and amendment are fully considered and found persuasive and the rejection is withdrawn herein in view of the amendment.
6. With regard to the rejection of claims 22-23, 31, 36, 40-41, 42 under 35 USC 102(b) as being anticipated by Mazzulli et al. , Applicants' arguments are fully considered and found persuasive regarding the characterization of a capture probe as a carrier probe and the rejection is withdrawn herein in persuasive arguments drawn to carrier probe. Examiner mischaracterized the capture probe as carrier calibrators, however, after a careful review of the reference it is noted the probe mix (unlabeled RNA probes) is different from the calibrator carrier DNA. Thus the rejections are re-written to address the issues raised in the arguments.

7. With regard to the rejection of claims 24, 26-27, 34-35, 43-45 under 35 USC 103(a) as being obvious over Mazzulli in view of Brakel et al., Applicants' arguments regarding the carrier probe are considered and the rejection is withdrawn herein and re-written to address the issues raised in the arguments.

8. With regard to the rejection of claims 28-30, 33 under 35 USC 103(a) as being obvious over Mazzulli in view of Collins et al., Applicants' arguments regarding the carrier probe are considered and the rejection is withdrawn herein and re-written to address the issues raised in the arguments.

9. With regard to the rejection of claims 1-24, 26-36, 38-46, 48-55 under provisional double patenting, Applicants' arguments are fully considered, however, the rejection is maintained herein since the instant claims are within the scope of the claims in the co-pending application.

Conclusion

Claims 1-21, 32, 38-39, 46, 48-55 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M. Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Suryaprabha Chunduru
SURYAPRABHA CHUNDURU 10/2/07
PRIMARY EXAMINER